IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors:	Törmälä et al.
Serial No.:	08/921,533
Filing Date:	September 2, 1997
For:	BIOACTIVE AND BIODEGRADABLE COMPOSITES OF POLYMERS AND CERAMICS OR GLASSES AND METHOD TO MANUFACTURE SUCH COMPOSITES
Examiner:	Lakshmi S. Channavajjala
Art Unit:	1615

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APPEAL BRIEF UNDER 37 C.F.R. 41.37 IN RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

SIR:

Appellants hereby submit this Revised Appeal Brief in response to the Notification of Non-Compliant Appeal Brief of August 15, 2007, for which a response is due on or before September 17 (September 15 being a Saturday). Particularly, the Notification states that the claimed invention "is not mapped to the independent claims on appeal, which shall refer to the specification by page and line number and to the drawings, if any." The Notification further states that only the section including such description need be filed. As such, Appellants are hereby submitting a revised "Summary of Claimed Subject Matter" section. The appeal brief fee was already paid on September 8, 2005, so Applicants believe no further fee is due in this respect. However, if any further fee is due, the Office is authorized to charge Kenyon & Kenyon's Deposit Account No. 11-0600 for such fees.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to a biodegradable and bioactive composite material comprising two different reinforcing phases and one matrix phase. One reinforcing phase is a resorbable polymeric reinforcing component and the other reinforcing phase is a ceramic reinforcing component mixed with the matrix component (phase). (See page 5, lines 17-19 and Figure 1).

The resorbable polymeric reinforcing component can be a fibrillated biodegradable or bioerodible polymer and the diameter of the reinforcing fibers can vary from between 4 microns and 800 microns, and preferably between 20 microns and 500 microns. The polymeric reinforcing component can be used as plain fiber or in modified form such as braided or woven into two or three dimensional structures. (See page 7, lines 10-11). Table 1 of the specification provides a list of resorbable polymers that can be used for the resorbable polymeric reinforcing component. (See pages 14-15).

The ceramic reinforcing component can comprise of bioceramic or bioglass, or a mixture of these and acts as a bioactive, bony ongrowth agent that provides a reservoir of calcium and phosphate ions, thus accelerating the healing time for bony fractures. While the matrix polymer degrades, bone can attach to the residual ceramic or glass particles. (See page 6, lines 9-11). The ceramic reinforcing component has a particle size of between 60 microns and 150 microns. (See page 6, line 7). As described by the specification:

> The defined particle size of the ceramic element in the composite described in this invention is relatively big compared to conventionally used particle sizes for fillers or granules. In this invention, it was found unexpectedly that composites having bigger particle size ceramic elements are more biocompatible and cause less irritation to tissue than composites utilizing a ceramic element having small particle size. Biocompatibility is easily seen in histological studies. In tissue near and inside the degrading composite implants having small ceramic particles[,] there exists more giant cells than around and inside the degrading composite implants containing big (coarser) ceramic particles.
>
> Page 6, lines 14-22.

This biocompatibility is also reported in Example 11 where two sets of sample plates of a composite material with a polymeric matrix component, a resorbable polymeric reinforcing component and a bioglass or bioceramic component (hydroxyapatite) were compared. The mean particle diameter of hydroxyapatite powder in the first set of plates was 7.43 microns and in the second set of plates was 80 ±20

microns. (See page 13, lines 9-16). Histology studies of ten animals showed that in and around the composite plates from the first set, there existed significantly more giant cells than in the tissue of animals implanted with the composite plates from the second set. See page 13, lines 18-22. Thus, the hydroxyapatite particles of 80 ±20 microns were shown to be more biocompatible. (See page 13, lines 22-23).

The amount of the ceramic reinforcing component can be 0.15 to 0.9 volume fraction and preferably between 0.2 and 0.6 volume fraction. Table 2 of the specification provides a list of bioceramics and bioglasses that can be used for the ceramic reinforcing component. (See page 15 to 16). The bioceramics or bioglasses can be in the form of a powder, flake, sphere, fiber, or other forms. (See page 6, line 6).

The composite material can contain various additives and modifiers which improve the processability of the composite. (See page 6, lines 23-24). Such additives include surface modifiers to improve the attachment between the polymeric and ceramic components. (See page 6, line 23 to page 7, line 1). The composite can also contain pharmaceutically active agents such as antibiotics, chemotherapeutic agents, wound-healing agents, growth hormones, and anti-coagulants. Such agents are used to enhance the bioactive features of the composite and improve the healing process of the tissue. (See page 7, lines 2-5).

The composite materials of the present invention have improved mechanical properties compared to non-reinforced devices because the reinforcement changes the behavior of the material from brittle to ductile and makes the device more reliable under load. (See page 4, lines 20-23).

The present invention also provides a method of manufacturing a composite material as described above. The polymer matrix component and the ceramic reinforcing component can be mixed together by powder mixing, melt mixing, or solvent mixing. (See page 7, lines 7-9). The mixture of the polymeric matrix component and the ceramic reinforcing component can be combined with the polymeric reinforcing component by melt mixing, by coating, or by using solvent as an intermediate to preform the material. (See page 7, lines 11-13). The material can be produced in its final form by various techniques including compression molding, filament winding, mechanical machining, or injection molding to any desired shape. (See page 7, lines 14-16).

Specifically, claim 1 is directed to a biodegradable and bioactive composite material for surgical osteosynthesis application. The composite comprises (i) at least one

resorbable polymeric matrix component; (ii) at least one resorbable polymeric reinforcing component and (iii) at least one bioceramic or bioglass reinforcing component mixed with said matrix component. (See Figure 1 and specification page 4, lines 11-19). The bioceramic or bioglass reinforcing component has a particle size between 60 μm and 150μm. (See specification, page 6, line 4-7).

Claim 16 is directed to a biodegradable and bioactive composite material for surgical osteosynthesis applications. The composite material comprises (i) at least one resorbable polymeric matrix component; (ii) at least one resorbable polymeric reinforcing component and (iii) at least one bioceramic or bioglass reinforcing component mixed with said matrix component. (See Figure 1 and specification page 4, lines 11-19). The at least one resorbable polymeric reinforcing component is in fiber form. (See specification, page 4, line 17-18). The diameter of the resorbable polymeric reinforcing component is greater than the diameter or particle size of the bioceramic or bioglass reinforcing component. (See specification, page 6, line 7-9). The bioceramic or bioglass reinforcing component has a particle size between 60 μm and 150μm. (See specification, page 6, line 4-7).

CONCLUSION

Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the Examiner's decision rejecting claims 1-6 and 9-22 and direct the Examiner to pass the case to issue.

Respectfully submitted,

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